JUN 2 5 2010

MEDTRONIC Sofamor Danek
CORNERSTONE® PSR Spinal System
Cervical Interbody Fusion Device
June 2010 – K100214

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** CORNERSTONE® PSR Spinal System
Regulation Name: Spinal Intervertebral Body Orthosis
Cervical Interbody Fusion Device
Classification: 21 CFR 888.3080 – Product Code: ODP

III. **Description:** The CORNERSTONE® PSR Spinal System is designed for use as a cervical intervertebral body fusion device. The device is manufactured from medical grade polyetheretherketone (PEEK) and is to be used with autograft.

The device has four degrees of lordosis. The lateral walls of the device contain openings to allow for the incorporation of bone during the fusion process. The superior and inferior surfaces of the implant are designed with teeth which interact with the surface of the vertebral endplates and helps in resisting backout.

IV. **Indications for Use:** The CORNERSTONE® PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE PSR device is also required to be used with autograft and is to be implanted via an open, anterior approach.

V. **Performance Data:** The following pre-clinical studies were conducted using worst case CORNERSTONE® PSR devices: static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077; as well

as subsidence testing per ASTM F2267. The results of these studies were found to be substantially equivalent to legally marketed devices.

VI. **Substantial Equivalence:** Documentation was provided which demonstrated that the subject device is substantially equivalent to previously approved devices such as the PEEK PREVAIL™ Cervical Interbody Device (K073285, SE 05/15/08), the AFFINITY® Anterior Cervical Cage (P000028, Approved - 06/13/2002), the BAK/C® Cervical Interbody Fusion System (P980048, Approved – 04/20/2001); the LDR ROI-C Cervical Interbody Fusion Device (K091088, SE 07/14/09); Biomet Spine's C-Thru Cervical Interbody Fusion Device, (K092336, SE 10/15/09; and the VERTE-STACK® Spinal System (K041197, SE 08/09/04). Documentation included mechanical test results

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 2 6 2010

Medtronic Sofamor Danek, Inc.
% Mr. Lee Grant
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K100214
Trade/Device Name: CORNERSTONE® PSR Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 16, 2010
Received: June 18, 2010

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K100214

Device Name: CORNERSTONE® PSR Spinal System

Indications for Use: The CORNERSTONE® PSR device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autograft and is to be implanted via an open, anterior approach.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100214